510(k) Summary

Trade Name: **Stern IC Dental Implant System**

Sponsor: Sterngold Dental, LLC
23 Frank Mossberg Drive
Attleboro, MA 02703

Contact: Maria Rao, QA/RA Director
Ph: 508-226-5660 ext 1206

Device Generic Name: Dental endosseous implant system

Classification: According to Section 513 of the Federal Food, Drug, and Cosmetic Act, the device classification is Class III

Product Code: DZE (21CFR872.3640)

Predicate Devices:
The Stern IC Dental Implant System is substantially equivalent to other currently marketed dental implant systems that have been cleared by FDA through the 510(k) Premarket Notification process, including the Sterngold Acid Etch Dental Implant System, and Straumann ITI Dental Implant System.

Product Description:
The Stern IC Dental Implant device is a root-form dental implant with a screw-type body, acid etched except for the neck of the implant, which is machined to a smooth finish. It is manufactured from pure grade 4 titanium with a flared neck, used for one-stage, transgingival or subgingival implantation. The neck and body include an internal taper and octagon. The implants are composed of grade 4 commercially pure titanium and are available in a range of lengths and diameters.
The acid etch surface is identical to the Sterngold Acid Etch Dental Implant System and the implant design is identical to Straumann's ITI dental implant.

The Stern IC Dental Implant System is compatible with Sterngold Acid Etch Dental Implant System, Straumann ITI Implant System. The proposed implant provides for non-rotational single and multiple tooth restorations in both the maxilla and mandible. Its single stage surgical procedure allows for immediate loading reducing chair time and patient trauma.
The proposed Stern IC dental implant has the same material composition and same surface treatment as previously cleared Sterngold Acid Etch dental implants.
The acid etched surface previously approved per Sterngold 510K submission K023580 is acid etched to achieve a slightly roughened microsurface to aid in implant osseointegration. This is the same process as the proposed Stern IC dental implant.

This submission also includes healing abutments, solid abutments, and cover screws which are used as accessories to the dental implants.
The implant components are manufactured from pure, implant-grade titanium alloy and are equivalent in terms of materials, performance specifications, manufacturing, manufacturing equipment, packaging materials and design as other Sterngold abutments and cover screws previously approved via K892124 and K924219.
The Stern IC Dental Implants and abutments are compatible with the Straumann Rn Synocta (K073628), Straumann SynOcta Meso Abutments (K033243), Straumann RC Temporary Abutments, (K093027) and the Straumann RC Cementable abutments (K072071).
The Stern IC Dental Implant System is not intended for correction of implant fixtures placed at an angle. It is only intended for use with straight abutments.

The proposed Stern IC Dental Implant will be available in a range of lengths and diameters.

Thread Major Diameter (mm)	Overall Implant Length (mm)	Neck/Cuff (mm)
3.3, 4.1mm	8.0, 10.0, 12.0, 14.0 mm	1.8mm

The 3.3 thread major diameter consists of the minor diameter .108+/-.001, thread height .0075 and R.0035X2 (each side of thread). This equals 0.13 inches = 3.3mm.
Thread Depth is .011 inches.

The 4.1 thread major diameter consists of the minor diameter .135+/-.001, thread height .0085 and R.0035X2 (each side of thread). This equals 0.16 inches = 4.1mm.
Thread Depth is .012 inches.

The Stern IC Solid Abutments are available in 4mm, 5.5mm and 7mm cuff.
The Stern IC RN Healing Abutments are available in 2mm and 3mm cuff.

Indications for Use:
The Stern IC Dental implant System is intended for long term surgical implantation in the bone of the patient's upper or lower arch to provide immediate load or delayed load of prosthetic systems, such as artificial teeth, in order to restore the patient's chewing function.
The Stern IC Dental Implant System is also indicated for immediate loading with good primary stability and appropriate occlusal loading.
The Stern IC Dental Implants are compatible with the Straumann Rn Synocta, Straumann SynOcta Meso Abutments, Straumann RC Temporary Abutments, and the Straumann RC Cementable abutments.
The Stern IC Dental Implant System is only intended for use with straight abutments.

Substantial Equivalence:
The proposed Stern IC Dental implants are substantially equivalent to other currently marketed dental implant systems that have been cleared by FDA through the 510(k) Premarket Notification process.

Sterngold Acid Etch Dental Implant System (K023580)
Straumann ITI Dental Implant System (K012757)

Technological Characteristics:
The proposed Stern IC Dental Implant is substantially equivalent to the previously cleared Sterngold Acid Etch Implant, and Straumann ITI implant. The intended use is identical to these predicate devices. The Straumann ITI implant is cleared for immediate or delayed loading in the maxillary and/or mandibular arches to support crowns, bridges or overdentures. This is the same intended use as the subject Stern IC dental implant.

The proposed Stern IC dental implant has the same materials and same acid etch process as previously cleared Sterngold Acid Etch dental implant. The new grit blast surface is substantially equivalent to Straumann's SLA implant.
This surface is widely used in the industry primarily by the Straumann Company under the name "SLA".

The residue is removed following the ASTM F86-04 (specifically section 7) protocol for final surface treatment.
In addition, the design of the Stern IC dental implant is mechanically identical to the previously cleared Straumann ITI implant.

Non-clinical Testing:
Non clinical Testing was performed following "Guidance for Industry and FDA Staff -Class 11 Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Abutments." Performance testing demonstrated that the device performs appropriately for the proposed indications for use.
Fatigue testing is not required because design features and technological features are substantially equivalent to predicate devices.
SEM photographs are enclosed showing all residue of the blasting material removed from the surface.
The enclosed surface chemical analysis confirms that no contaminants are left on the surface. This surface analysis was conducted on the final device.

Conclusion:
Based on our analysis, the device is substantially equivalent in intended use, material, design and performance to its predicate devices, Sterngold Acid Etch Dental Implant System (K023580) and Straumann ITI Dental Implant System (K012757) and it is considered to be substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUN - 1 2012

Ms. Maria Rao
Quality Assurance / Regulatory Affairs Director
Strengold Dental, LLC
23 Frank Mossberg Drive
Attleboro, Massachusetts 02703

Re: K111798
Trade/Device Name: Stern IC Dental Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE, NHA
Dated: May 23, 2012
Received: May 23, 2012

Dear Ms. Rao:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

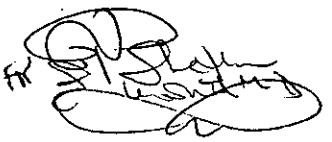
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K111798

Device Name: Stern IC Dental Implant System

Indications for Use:

The Stern IC Dental implant System is intended for long term surgical implantation in the bone of the patient's upper or lower arch to provide immediate load or delayed load of prosthetic systems, such as artificial teeth, in order to restore the patient's chewing function.
The Stern IC Dental Implant System is also indicated for immediate loading with good primary stability and appropriate occlusal loading.

The Stern IC Dental Implants are compatible with the Straumann Rn Synocta , Straumann SynOcta Meso Abutments, Straumann RC Temporary Abutments, and the Straumann RC Cementable abutments.
The Stern IC Dental Implant System is only intended for use with straight abutments.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use __X__ AND/OR Over-the -Counter Use ____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart D)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K111798